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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,491	07/17/2006	Peter Fritzson	BERGLUNDS P0412	1438

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EXAMINER	
RIGGS II, LARRY D	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,491	FRITZSON ET AL.	
	Examiner	Art Unit	
	LARRY D. RIGGS II	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07 May 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's preliminary amendment filed 21 April 2006 is acknowledged and entered.

Priority

Applicant's claim for the benefit of a prior-filed applications PCT/SE04/01524 filed 21 October 2004 and 0302815-6 filed 24 October 2003, under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged and accepted.

Information Disclosure Statement

The information disclosure statement filed 07 May 2007 is acknowledged. A signed copy of the corresponding 1449 form has been included with this Office action.

Drawings

The drawings filed on 21 April 2006 are acceptable.

Claim Objections

Claims 23-26 are objected to because of the following informalities: The instant claims provide "the method of claim 17". However, claim 17 is an automatic dosage device (an apparatus) and not drawn to a process.. Claims 23-26 are interpreted to depend from method claim 19 and thus the instant claims should be amended so as to recite "the method of claim 19". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-28 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The recent en banc decision regarding Bilski v. Warsaw (2008) set forth that a process is patent-eligible if (1) it is ties to a particular machine or apparatus or (2) it transforms a particular article into a different state or thing.

The instant claims are drawn to a method for determining drug dosage. The instant claims are drawn to the abstract process steps of receiving data regarding a patient's biochemical profile, receiving data regarding property of a drug, simulating the effect of a dosage of the drug, determining a drug dosage for the patient based on the simulation.

The instant claims do not recite or inherently involve any transformation of an article, therefore the Examiner must determine if the instant claims have a tie to a particular machine or apparatus. Instant method claims 19-26 do not recite any limitation that ties the recited abstract process to any particular machine or apparatus. Further, claim 28 only recites a computer readable medium comprising executable instructions for carrying out said abstract process, and therefore reads on a general apparatus that would preempt the abstract process. Similarly, claims 1-18 recites an apparatus comprising an input interface and a processor comprising a simulation and

evaluation modules, and a dosage apparatus comprising a measuring unit. As such, the apparatus and dosage apparatus are not a particular machine or apparatus, as its only function would preempt the abstract process as set forth above.

Further, displaying said interval scores is an insignificant post-solution activity. Nominal or token recitations will not suffice, E.g. displaying, inputting, obtaining, See Ex parte Langemyr (May 28, 2008). Applicants are cautioned against introduction of new matter in an amendment.

Since the instant method claims 19-26, do not provide a physical transformation, the Examiner must determine if the instant claims produce a useful, tangible, and concrete final result. In determining if the instant claims have a useful, tangible, and concrete final result, the Examiner must determine each standard individually. For a claim to be "useful", the claim must produce a final result that is specific, substantial and credible. For a claim to be "tangible", the claim must set forth a practical application of the invention that produces a real-world final result. For a claim to be "concrete", the process must have a final result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete final result in the claim itself, and the claim must be limited only to statutory embodiments. Thus if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

Method claims 19-26 do not produce a tangible final result. A tangible requirement requires that the claim must set forth a practical application of classifying

the test sample, to produce a real-world result. The instant claims are drawn to a method for determining a drug dosage. However, the last step of the claim determines a dosage of the drug for the patient based on the simulation, wherein the determined dosage is just data and thus no tangible result. Since the claim itself must include a useful, concrete and tangible final result, the instant claims are non-statutory.

Regarding the apparatus claims 1-18 and computer readable medium claim 28, because the method claims are drawn to nonstatutory subject matter for not producing a useful, concrete and tangible result, the systems that perform the process also do not produce a useful concrete and tangible result, thus also drawn to nonstatutory subject matter.

This rejection could be overcome by amendment of the claims to recite that a specific final result of the process is outputted to a user, or by including a result that is a physical transformation. The applicants are cautioned against introduction of new matter in an amendment.

Claim 27 is directed to nonfunctional descriptive material.

Regarding claim 27, software, per se, i.e. computer program, without being on a computer readable medium, is considered as nonfunctional descriptive material, and thus nonstatutory. See nonfunctional descriptive material under MPEP 2106.1.

For these reasons, claims 1-28 are considered non-statutory subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Zarowitz et al. (US 4,880,014).

The instant claims are drawn to a method for determining drug dosage comprising steps of receiving data regarding a patient's biochemical profile, receiving data regarding property of a drug, simulating the effect of a dosage of the drug, determining a drug dosage for the patient based on the simulation.

Regarding claim 19, Zarowitz et al. shows personal characteristics along with resistance and reactance of a patient are measured, pharmacokinetic parameters such as volume of distribution, elimination rate constant, and clearance for a particular drug are provided, these values are imput into a model wherein a drug dosage regimen is determined for the patient, (abstract, columns 4-12; Figure 1).

Regarding claim 20, Zarowitz et al. shows repeated dosage calculations based on clearance parameters and predicted parameters, (columns 17-19; Table VIII).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zarowitz et al. (US 4,880,014) as applied to claims 19 and 20 above, in view of Slotman (US 7,297,546).

The instant claims are drawn to a method for determining drug dosage comprising steps of receiving data regarding a patient's biochemical profile, receiving data regarding property of a drug, simulating the effect of a dosage of the drug,

determining a drug dosage for the patient based on the simulation. Further embodiments include repeating the simulation until a condition is met, patient parameters associated with metabolic pathways and from blood samples, and a relation between reactants and drug concentrations.

Zarowitz et al. is applied to claims 19 and 20 above.

Zarowitz et al. shows repeat modeling for a dosage but does not show repeating the simulation until a condition is met, patient parameters associated with metabolic pathways and from blood samples, and a relation between reactants and drug concentrations.

Regarding claims 21-26, Slotman shows obtaining a patient's SMART profile (Systemic Mediator-Associated Response Test) from selected patient parameters to predict the risk of developing systemic inflammatory condition in response to i.e. a treatment, agent, etc. (columns 7-8). Slotman shows patient parameters associated with metabolic pathways and from blood samples, i.e. nitric oxide metabolites, levels of alkaline phosphatase and complete blood count, (column 8).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of determining a dosage regimen by Zarowitz et al. by using the SMART profile of a patient by Slotman because Zarowitz et al. shows the importance of obtaining a therapeutic dosage regimen with optimum accuracy and reducing subtherapeutic or toxic drug dosages from inaccurate data, (column 4, second paragraph) and a person of ordinary skill in the art would understand that utilizing a patient's SMART profile to optimize a drug dosage would best be accomplished with the

modeled relationship of the SMART profile parameters and the drug concentrations resulting in an accurate, safe and therapeutic dosage for the patient. Therefore, one of ordinary skill in the art would recognize the claimed process as a combination of routine applications that are well known the art that and produce no more than expected results.

Claims 1-4, 11, 13-18, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zarowitz et al. (US 4,880,014) in view of Slotman (US 7,297,546) as applied to claims 19-26 above.

The instant claims are drawn to an apparatus, computer program and computer readable medium for determining a drug dosage.

In *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958), the court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplish the same result is not sufficient to distinguish over the prior art (see also *Manual of Patent Examining Procedure,* U.S. Trademark and Patent Office, section 2144.04, III).

In the instant case, the claimed invention merely makes the process of Zarowitz et al. in view of Slotman as computer-implemented or automatic and indeed accomplishes the same result. It is thus not sufficient to distinguish over Zarowitz et al. in view of Slotman. Therefore, the claimed invention, i.e. the apparatus, computer program and computer readable medium comprising instructions to execute a process

would have been obvious to a person of ordinary skill in the art at the time the invention was made over the process disclosed by Zarowitz et al. in view of Slotman.

Furthermore, while Zarowitz et al. do not explicitly disclose such an apparatus or computer medium comprising instructions for executing all the steps of the process as in claim 19, Slotman discloses automated apparatus for determining various patient paratmeters, (column 9, last paragraph; column 18, last paragraph). Thus they at least disclose a the importance of using automated machinery to obtaining patient parameters. Thus, the entire method of Zarowitz et al. in view of Slotman could be interpreted as semi-automatic. One of ordinary skill in the art would have been motivated to make it completely automatic by providing an apparatus or system comprising instructions in the computer readable medium for executing all steps of the method to take the obvious advantage of a fully automatic process, i.e. saving time and cost.

There would have been a reasonable expectation of success because the court held regarding software that "writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed." Fonar Corp., 107 F.3d at 1549, 41 USPQ2d at 1805.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY D. RIGGS II whose telephone number is

(571)270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S DeJong/
Examiner, Art Unit 1631

/LDR/
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